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10/661,159	09/12/2003	Jaime Salvador Vargas	ENDOV-001/US	6784

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PATENT DEPT  
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EXAMINER
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HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/661,159	<b>Applicant(s)</b> VARGAS, JAIME SALVADOR	
	<b>Examiner</b> JEFFREY G. HOEKSTRA	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18-55 is/are pending in the application.
- 4a) Of the above claim(s) 19-25 and 31-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/11/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Notice of Amendment***

1. In response to the amendment(s) filed on 11/12/2008 and 12/09/2008, amended claim(s) 19 and 41 is/are acknowledged. The current objections and/or rejections is/are *withdrawn*. The following new is/are set forth:

### ***Election/Restrictions***

2. Applicant's election with traverse of Group II, drawn to the rigidizing linkage mechanisms of claims 19-30 and 50-53 in the reply filed on 12/09/2008 is acknowledged. The traversal is on the ground(s) that (a) claims 35, 40, 41, 42, 45, 48, and 47 are drawn to "rigidizing mechanisms" not "linkage structures" and (b) claim 50 is drawn to a "linkage structure not a "rigidizing mechanism".

3. This is not found persuasive because (a) even though claims 35, 40, 41, 42, 45, 48, and 47 either directly or inherently recite structure for altering a sheath and/or core's flexibility, the scope of claims 35, 40, 41, 42, 45, 48, and 47 positively recite "A cannula system" in line 1 and are clearly directed towards the "a cannula system" combination, in addition the Examiner notes groups II is directed towards the "rigidizing linkage mechanism" subcombination not merely "rigidizing mechanisms" and/or "linkage structures" and (b) claim 50 positively recites within the scope of invention structure for linking and/or rigidizing and as such the scope of the invention is drawn towards the "rigidizing linkage mechanism" subcombination and not the "cannula system" combination.

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4. Moreover, the Examiner notes Applicant's arguments are apparently directed towards a mischaracterization of the nature of the restriction (see page 2 mailed 10/29/2008). The inventions defined by Groups I and II were set forth as related by combination subcombination and inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it does not require a plurality of components for selectively rigidizing a length of the plurality of components. The subcombination has separate utility such as stiffening and un-stiffening within a bodily lumen.

5. The requirement is still deemed proper and is therefore made FINAL.

6. Claims 18, 31-49, and 54-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/09/2008.

7. Applicant's election of Species QQ, embodiment drawn to Figures 20A and 20B, in the reply filed on 12/09/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

8. Claims 19-25 and 50-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/09/2008.

9. However, the Examiner notes Applicant traverses the Examiner's assertion that no claims are generic (see page 7 mailed 10/29/2008). Applicant argues with respect to group II that claims 21 and 26 are generic. The Examiner disagrees and maintains no claims appear generic to the species set forth in the election of species requirement mailed 10/29/2008.

10. For record clarity and reference, the Examiner reproduces a portion of the instant Specification within which appears to be the detailed disclosure of the elected embodiment drawn to Figures 20A and 20b, paragraph 67 reads as follows:

11. *"[0067] In another embodiment of the invention, FIG. 22 depicts rigidizing structures including inner and outer concentric tubes, 221 and 222 respectively, separated by short segments of materials 223 that change shape when energized, such as electroactive polymer (EAP), which changes shape when exposed to electric fields. The inner tube 221 may or may not have an open lumen. When employing biaxially active materials such as EAP, the active material components are oriented to contract longitudinally and expand radially when energized. The active material components may be employed in a normally-non-interfering configuration or a normally-interfering configuration. In a normally-non-interfering configuration the active material components 223 are each attached to one of the concentric tubes 221 or 222 such that they do not contact the other tube, as shown in FIG. 20a, when not energized. When energized, the radial expansion of the active material components 223 causes mechanical interference with the other tube, as in FIG. 20b, thus preventing motion between the opposed surfaces 224 and 225 and effectively locking-in the curvature of the rigidizing structure. According to the present*

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*invention, one may substitute materials that change shape when exposed to electric current, magnetic fields, light, or other energy sources. The same rigidizing effect may be achieved by replacing normally-non-interfering active material components 223 with non-interfering balloons expandable by gas or liquid fluid pressure. Alternately, such materials may be placed in a normally-interfering configuration between concentric tubes 221 and 222 such that they interfere, as in FIG. 20b when not energized and contract radially to the state depicted in FIG. 20a when energized. For example, a normally-rigid structure made stiff by normally-interfering EAP components 223 may be made flexible by applying a voltage to the EAP components such that they contract radially to the non-interfering state depicted in FIG. 20a, relieving the mechanical interference and allowing relative motion between the opposed surfaces 224 and 225 of the concentric tubes 221 and 222. Similarly, normally-interfering balloons replacing normally-interfering active material components 223 may be collapsed by applying a relative vacuum. "*

12. Finally, the Examiner vacates the election of Species for Set 3 as set forth in paragraph 10 page 6 mailed 10/29/2008 as the Species Set 3 election is no longer applicable in lieu of Applicants election of Species QQ.

### ***Information Disclosure Statement***

13. The information disclosure statement(s) (IDS) submitted on 12/11/2008 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

### ***Drawings***

14. The drawings were received on 12/10/2008. These drawings are acceptable.

***Specification***

15. The disclosure is objected to because of the following informalities: Paragraph 67 positively refers to Figure 22, however it appears it should positively refer to Figures 20A and 20B. Appropriate correction is required.

16. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 102***

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 26 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Bauerfeind et al. (US 5,337,733, hereinafter Bauerfeind).

19. For claim 26, Bauerfeind discloses a rigidizing mechanism (14) (as best seen in Figure 1 and 2), comprising *inter alia*:

- an inner element (16) (as best seen in Figure 1 and 2) (column 5 lines 5-47) and an outer element (18) (as best seen in Figure 1 and 2) (column 5 lines 5-47) positioned concentrically around the inner element (as best seen in Figure 1 and 2), wherein

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the inner and outer elements are flexible (as best seen in Figures 3a-3f) (column 5 lines 36-38); and

- a plurality of components (32 and 36) (as best seen in Figure 1 and 2) positioned between the inner and outer elements (as best seen in Figure 1 and 2),
- wherein in a first state (column 5 lines 47-63) the components interfere between the inner and outer elements with a force sufficient to prevent the inner and outer elements from moving relative to one another (column 5 lines 47-63), and in a second state (column 5 lines 47-63) the components do not significantly interfere between the inner and outer elements (column 5 lines 47-63).

20. For claim 28. , Bauerfeind discloses a mechanism, wherein the components comprise balloons (32 and 36) (as best seen in Figure 1 and 2) (column 5 lines 47-63).

21. For claim 29, Bauerfeind discloses a mechanism, wherein the components are energized and expanded radially in the first state (column 5 lines 47-63).

22. For claim 30, Bauerfeind discloses a mechanism, wherein the components are energized and contracted radially in the second state (column 5 lines 47-63).

### ***Claim Rejections - 35 USC § 103***

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



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24. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bauerfeind. Bauerfeind discloses the claimed invention, a set forth and cited above, except for expressly disclosing the components comprise an electroactive polymer. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the rigidizing mechanism comprising expanding components comprising gas/fluid expandable components as taught by Bauerfeind with the electroactive polymer, because Applicant has not disclosed that the electroactive polymer provides an advantage, is used for a particular purpose, or solve a stated problem (see paragraph 11 above). One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with rigidizing mechanism comprising expanding components comprising gas/fluid expandable components as taught by Bauerfeind (see paragraph 11 above), because it provides a first state where the components interfere between the inner and outer elements with a force sufficient to prevent the inner and outer elements from moving relative to one another, and a second state where the components do not significantly interfere between the inner and outer elements (see paragraph 11 above) and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Bauerfeind (see paragraph 11 above). Therefore, it would have been an obvious matter of design choice to modify Bauerfeind to obtain the invention as specified in the claim(s).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736